

### **REMARKS**

According to the Office Action of June 27, 2007, the rejection of pending claims 20-39 as unpatentable under 35 U.S.C. § 103 has been maintained. The Applicants have amended claims 20, 22-24, 26-31, 35 and 38 and have cancelled claim 21. Due to this cancellation, claims 20 and 22-39 are presently pending. In view of the amendments to the claims and the remarks below, Applicants respectfully request reconsideration and withdrawal of the objections and rejections.

#### **I. REJECTION OF CLAIMS 20, 22-28, 31, 35 AND 36**

Specifically, claims 20, 22-28, 31, 35 and 36 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ayre<sup>1</sup> in view of Suzuki<sup>2</sup>.

##### **A. THE RECITED INVENTION**

Amended claim 20 is directed to a sampler for taking a sample from a body cavity. The sampler has a tubular means adapted to be introduced in said cavity. A storage means is connected to the tubular means. A vacuum means connected to the storage means and/or the tubular means. The tubular means has a rigid tube with a diameter of at least 1 cm and a curved introduction end. The rigid tube provides a closure in the body cavity. There are a number of sampling openings provided only at the curved introduction end. One of these openings is a central opening having a diameter of less than 5 mm. The sampler further has a liquid containing means and a pump means. The liquid containing means contains a flushing solution, which is expelled through the curved introduction end by the pump means. Claims 22-28 depend from claim 20.

Claim 31 is directed to a sampler assembly that includes a sampler for taking a sample from a body cavity. The sampler has a tubular means adapted to be introduced in the cavity. A storage means is connected to the tubular means. A vacuum means is connected to the storage means and/or the tubular means. The tubular means has a rigid tube with a diameter of at least 1 cm and a curved introduction end. A number of sampling openings are provided only at the curved introduction end. The openings include a central opening having

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<sup>1</sup> United States Patent Number 3,540,432 to Ayre ("Ayre").

a diameter of less than 5 mm. The sampler also includes a liquid containing means and a pump means. The liquid containing means contains a flushing solution, which is expelled through the introduction end by the pump means.

Claim 35 is directed to a method for taking a sample from a body cavity comprising introducing a sampler tube into the entrance of the cavity. The sampler tube includes a tubular means adapted to be introduced in said cavity. A storage means is connected to said tubular means. A vacuum means is connected to the storage means and/or the tubular means. The tubular means has a rigid tube with a diameter of at least 1 cm and a curved introduction end. A number of sampling openings is provided only at the curved introduction end. The openings include a central opening having a diameter of less than 5 mm. The sampler tube also includes a liquid containing means and a pump means. The sampler tube also includes a liquid containing means and a pump means. The liquid containing means contains a flushing solution, which is expelled through the curved introduction end by the pump means. The sampler tube is moved into the cavity, up into contact with a blind end of the cavity. The flushing solution is expelled into said body cavity. A sample is taken by suctioning the sample at the end of the sampler tube through the openings. Claim 36 depends from claim 35.

#### **B. THE CITED REFERENCES**

Ayre is directed to a cytological instrument having a straight tube 5 provided with a scraping and aspiration head 7. The head 7 is provided with aspiration holes 11 and upstanding ribs 10. One of ordinary skill would use the glycerine taught in Ayre as a coating on the interior and exterior of the conically shaped surface 7.<sup>3</sup> The ribs 10 are formed to scrape cells from a lesion in the vaginal cavity, resulting in desquamation of cells, many of which may then adhere to the coating on the head 7.<sup>4</sup> The bulb 6 is initially squeezed to expel air from the cytological instrument through the holes 11.<sup>5</sup> This creates a vacuum when retrieving the instrument from the vaginal cavity, allowing cells scraped from the cervix and

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<sup>2</sup> United States Patent Number 4,781,699 to Suzuki *et al.* ("Suzuki").

<sup>3</sup> Ayre at column 2, lines 14-22.

<sup>4</sup> Ayre at column 2, lines 38-40.

<sup>5</sup> Ayre at column 2, lines 35-37.

desequimated into the mucus from the cervical or uterine lesion to be aspirated into the head 7.<sup>6</sup>

Unlike the recited invention, Ayre does not disclose the presence of a number of sampling openings 46 including a central opening 47 in a curved introduction end 48 of a rigid tube 44. Ayre's holes 11 are only provided on the conically shaped surface of the head 7 between the ribs 10, not on a curved introduction end. The dimensions and construction details make the sampler according to the present invention suitable for expelling a flushing solution, closing off a closure in the body cavity, and using a flushing solution to obtain cells from the body cavity in order to allow recollection of the flushing solution with cells.

The Office Action acknowledges that Ayre does not disclose the recited opening that is less than 5 mm in diameter, the vacuum means comprising a pump means, the vacuum means comprising a plunger cylinder, or the tube comprising a cylinder.<sup>7</sup> To overcome these deficiencies, the Office Action cites Suzuki,<sup>8</sup> which is directed to a mucus-removing device. Suzuki's device is intended to introduce the catheter at the tip of the device into an uterocervical canal of an animal, particularly a cow, to suck away mucus from the canal. Mucus interferes with the collection of embryo's during embryo transfer. Thus, Suzuki is in a different field of endeavor from the Ayre and the claimed invention.

### C. THE RECITED INVENTION IS PATENTABLE OVER THE CITED REFERENCES

The recited invention is patentable over the cited references because the cited references do not teach the flushing solution or the expelling step, because there is no reason to combine the references in a manner that results in the recited invention and because Suzuki is a non-analogous reference.

#### 1. The cited references do not teach the recited flushing solution or the recited expelling step.

When making a rejection under 35 U.S.C. § 103, the Patent Office has the burden of establishing a *prima facie* case of obviousness. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, the references must be

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<sup>6</sup> Ayre at column 2, lines 40-45.

<sup>7</sup> Office Action at page 3.

evaluated based on what each, as a whole, teaches to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392 (CCPA 1971). To establish this, each and every claimed element must be taught or made obvious by the applied references. *Ex parte Likins*, Application No. 10/010,392, Appeal No. 2004-0760, 2004 WL 4981756 at \*3 (BPAI Apr. 8, 2004).

In this case, the claims (as amended) recite “a liquid containing means and a pump means to expel a flushing solution from said liquid containing means through said curved introduction end of said rigid tube.” The combination of the cited references does not fairly teach or suggest a flushing solution or expelling a flushing solution. The glycerine disclosed in Ayre is not a flushing solution. One of ordinary skill would use Ayre’s glycerine to coat the interior and exterior of Ayre’s conically shaped surface.<sup>9</sup> Furthermore, the glycerine is not expelled from Ayre. Instead, air is expelled when using Ayre’s device.<sup>10</sup>

The Office Action contends that “one of ordinary skill in the art would have been able to determine that the charge of glycerine in the head of the device would be expelled in the vagina once the bulb is squeezed, thus acting as a flushing solution.”<sup>11</sup> However, this is inconsistent with the literal statement within Ayre regarding the events that follow squeezing the bulb: “When completely inserted, the bulb of the tube is grasped and squeezed *to expel air* and to create a vacuum around the head of the instrument.”<sup>12</sup>

Ayre also does not disclose a number of sampling openings that includes a central opening at the curved introduction end. The holes 11 in Ayre are only provided on the conically shaped surface of the head 7 between the ribs 10, and not on a curved introduction end.

Since Ayre does not fairly teach a flushing solution expelled from the sampler or a curved introduction end having a number of sampling openings that includes a central opening, the combination of the cited references, taken as a whole, do not fairly teach each

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<sup>8</sup> Office Action at page 3.

<sup>9</sup> Ayre at column 2, lines 14-22.

<sup>10</sup> Ayre at column 2, lines 35-37.

<sup>11</sup> Office Action at page 5.

<sup>12</sup> Ayre at column 2, lines 35-37 (emphasis added).

and every limitation recited in the claims. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

**2. There is no reason to combine the references in a manner that results in the recited invention.**

Even assuming that Ayre discloses these missing elements, there is no reason or motivation to combine the references in a manner that results in the recited invention. As part of a *prima facie* case, an examiner must establish some reason to combine the references. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007); *Takeda Chemical Industries, Ltd. v. Alpharpharm Pty., Ltd.*, 492 F.3d 1350, 1356-1357 (Fed. Cir. 2007). The *KSR* Court acknowledged the importance of identifying a reason that would have prompted a person of ordinary skill in the art to combine the elements in the way the claimed invention does. *KSR Int'l*, 127 S.Ct. at 1731; *Takeda Chemical*, 492 F.3d at 1356-1357. Repeatedly throughout the *KSR* decision, the Court discussed the importance that the result obtained by a particular combination was predictable to one of ordinary skill in the art. *KSR Int'l*, 127 S.Ct. at 1731 and 1739-1742. Mere conclusory statements are insufficient to establish the requisite reason to combine. See MPEP § 2141, citing *In re Kahn* 441, F.3d 977, 988 (Fed. Cir. 2006).

A combination of known elements will not yield predictable results if the references disclose a broad selection of compounds or combinations. See *Takeda Chemical*, 492 F.3d at 1359; also see *Ortho-McNeil Pharmaceutical, Inc. v. Mylan*, 520 F.3d 1358, 1364 (Fed. Cir. 2008); and also see *Ex parte Ikeda*, App. No. 08/352,079, Appeal 2008-0492, Slip Op. at 7 (BPAI Mar. 26, 2008). For example, in a recent case, the Board reversed an examiner's rejection for failing to provide the requisite reason to combine the references. *Ikeda*, App No. 08/352,079 at 7. The *Ikeda* application was directed to a method of removing hydrocarbons from exhaust gases. *Id.* at 2. In pertinent part, the claims recited an absorption catalyst B located downstream of a catalyst A in the direction of the exhaust gas. The claims were rejected as unpatentable under 35 U.S.C. § 103 in view of Swaroop, Abe and Patil. *Id.* at 3. Swaroop taught positioning the absorption catalyst B upstream catalyst A. *Id.* at 5. To remedy the deficiency in the art, the examiner cited "Patil and Abe as evidence of the 'conventionality of positioning the adsorbent catalyst 1 either upstream or downstream of a [three-way] catalyst 3' and thus conclude[d] that it would have been obvious to one of

ordinary skill in this art to select an appropriate location for the adsorbent catalyst 16 in the apparatus of Swaroop ....” *Id.* at 5-6. The Board held that

The Examiner has failed to provide any cogent reason or technical discussion to support the conclusion that one of ordinary skill in this art would have employed the relative positions of the catalysts in Abe and Patil without the use of the other teachings of these references, namely an auxiliary heater and bypass lines with valving. Second, the Examiner has not explained why one of ordinary skill in this art would have used the teachings of Patil, requiring bypass lines and valving, when Swaroop specifically teaches away from the use of valving and bypass lines [*citation omitted*]. Third, the Examiner has not supplied convincing reasoning or technical discussion to support the proposed switch in relative position of the catalysts when Swaroop specifically teaches that the exhaust gas is “modified” by the adsorbent catalyst and this modified form of the exhaust gas is *then* sent to the main or three-way catalyst to undergo conversion to innocuous products [*citation omitted*]. ... Fourth, the Examiner has not explained why one of ordinary skill in this art would have proceeded contrary to the teachings of Patil, namely the teachings that “it is not possible merely to place zeolite ‘in-line’ in the exhaust system with the [main] catalyst has reached an effective temperature and unconverted hydrocarbons would still be discharged to the atmosphere” [*citation omitted*].

*Ikeda*, App. No. 08/352,079 at 7.

Like *Ikeda*, a reason to combine the references in a manner that results in the recited invention has not been provided. There is no reason provided why one would move Suzuki’s sample openings, which are positioned along the side, to a curved introduction end let alone make the Suzuki sampling opening the central opening in a number of sample openings positioned only at the curved introduction end. There is no reason provided why one would use a smaller diameter opening. At best, the combination of Ayre and Suzuki would result in a sampler with a tubular structure having sampling openings over a large portion of the tube, or with sampling openings on a conically shaped head.

Due to the lack of the requisite reason to combine these references, the Applicants respectfully request reconsideration and withdrawal of these rejections.

### **3. Suzuki is a non-analogous reference.**

According to MPEP § 2141.01(a),

The examiner must determine what is “analogous prior art” for the purpose of analyzing the obviousness of the subject matter at issue. “Under the correct analysis, any need or problem known in the field of endeavor at the time of the

invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed." *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

In this case, Ayre and Suzuki do not address similar needs or problems and are from different fields of endeavor. Suzuki is directed to removing mucus from cows after embryogeny.<sup>13</sup> This is unrelated to Ayre's and the inventor's field of endeavor – sampling cells from the cervix.

Viewing Suzuki and Ayre both as a "sampling device" expands the field of endeavor to include animal veterinary medicine. Since Suzuki is directed to animal veterinary medicine, not gynecology, it is a non-analogous reference.

Since non-analogous references cannot be combined, the Applicants respectfully request reconsideration and withdrawal of these rejections.

## **II. REJECTION OF CLAIMS 29, 30, 31 and 37**

Claims 29, 30, 32 and 37 have been rejected as purportedly unpatentable over the combination of Ayre, Suzuki and Lurie<sup>14</sup>. These claims ultimately depend from independent claims 20, 31 or 35. Applicants respectfully traverse this rejection for the reasons discussed above, and because Lurie does not overcome any of the above-identified deficiencies.

Furthermore, Lurie is directed to a device for taking samples from a uterus, not a vaginal cavity. Such devices require a thinner catheter to be able to pass the cervical channel, and the construction of such devices is vastly different. Due to these differences, one would not find it obvious to use a vacuum means for retrieving samples from a uterus in a sampler for retrieving samples from the cervical samples.

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<sup>13</sup> Suzuki at abstract.

<sup>14</sup> United States Patent Number 7,207,951 to Lurie *et al.* ("Lurie").

**III. REJECTION OF CLAIMS 33 , 34, 38 AND 39**

Claims 33, 34, 38 and 39 have been rejected as purportedly unpatentable over the combination of Ayre, Suzuki and Oster<sup>15</sup>. These claims ultimately depend from claims 31 or 35. Applicants respectfully traverse this rejection for the reasons discussed above, and because Oster does not overcome any of the above-identified deficiencies.

**IV. CONCLUSION**

In view of the amendments and remarks, Applicants respectfully request that all objections and rejections be reconsidered and withdrawn, and that pending claims 20, and 22-39 be allowed. Should the Examiner wish to discuss this matter further, the Examiner is encouraged to contact the Applicants' undersigned representative at (412) 471-8815.

Respectfully submitted,

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<sup>15</sup> United States Patent Number 3,815,580 to Oster ("Oster").